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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,894	10/03/2005	Gopalan Selvaraj	PAT 753W-2	5250

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EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
06/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/522,894	SELVARAJ ET AL.	
	Examiner	Art Unit	
	LI ZHENG	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17,21,23,25,27 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17,21,23,25,27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 11-17 and 21, 23, 25, 27 and 29 are pending and examined on the merits.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2009 has been entered.

Applicant's cancellations of claims20, 22, 24, 26 and 28, amendments to claims 11-13, 16, 21, 23, 25, 27 and 29 filed on 4/8/09 are acknowledged.

Claims 11-17 and 21, 23, 25, 27 and 29 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejections and objections that are not recited in this Office Action are considered as being withdrawn.

Claim Rejections - 35 USC § 112

Scope of Enablement

5. Claim 11-17 and 21, 23, 25, 27 and 29 remain ejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an RNA hairpin construct comprising a promoter operably linked to sense-oriented nucleotide sequence of SEQ ID NO: 29, 30, 37 and 38 and antisense-oriented nucleotide sequence of SEQ ID NO: 29, 30, 37 and 38, a transgenic rice plant comprising a plant transformation vector encoding said RNA hairpin construct, as well as a method for producing a rice plant or plant cell having male sterility or modulated male fertility, does not reasonably provide enablement for said RNA hairpin construct wherein the RAFTIN1 is any other RAFTIN1 sequence, or any transgenic plant or cells comprising said plant transformation vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the

invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The instant claims are broadly drawn to an RNA hairpin construct comprising a promoter operably linked to sense-oriented nucleotide sequence of RAFTIN from wheat and rice, an intron and an antisense-oriented RAFTIN nucleotide sequence from wheat and rice, a transgenic plant, plant cell or seed comprising a transformation vector encoding the RNA hairpin construct, as well as a method for producing a plant having male sterility or modulated male fertility by transforming the transformation vector into plant cell.

The specification teaches isolation and characterization of the RAFTIN1 group of anther-tapetum specific genes, taRAFTIN1a, taRAFTIN1b and taRAFTIN1d in wheat and osRAFTIN1 in rice (page14, lines 18-21). Further BLASTX search of public gene database identify 12 ESTs from wheat, rice, barley, rye, sorghum and maize (the paragraph bridging pages 9-10). The specification further teaches that intron-spliced hairpin RNA using sense and antisense sequences of osRAFTIN1 or taRAFTIN1a reduces osRAFTIN1 expression in rice (Figure 7; also page 12, lines 3-25) and that down-regulation of osRAFTIN1 reduces male sterility in the transgenic rice (the paragraph bridging pages 12-13).

First , while it is true that reduced expression of osRAFTIN1 results in male sterility or modulated male fertility, it is unclear what the functions for three putative RAFTIN1 genes from wheat are. The putative role for those three putative RAFTIN1 genes in male fertility is only assumed from the sequence homology. The prior art

cannot *unambiguously* assign function to an unknown gene based on a homology comparison. The following example demonstrates that assignment of a metabolic gene to a known function based on homology comparisons alone provides improper functional assignment (see the homology-based methods of functional assignment of Everett et al., Nature Genetics *17*, 411-422, 1997 in light of the experimental conclusions of Scott et al., Nature Genetics *21*, 440-443, 1999). Everett et al. disclose a homology-based functional assignment to a putative, mutated sulfate transporter gene (PDS; which encodes "pendrin") identified through positional cloning in pendred syndrome populations. The homology-based searches were carried out using BLAST and PSI-BLAST with commercial databases using human pendrin as the query sequence. The conclusions of Everett et al. based upon the homology comparisons were that pendrin was a transporter of sulfate. However, experimental studies by Scott et al., clearly demonstrate that pendrin, which has: 1) 29% homology to the rat sulfate-ion transporter encoded by *Sat-1*; 2) 32% homology to the human diastrophic dysplasia sulfate transporter *DTD*; and 3) 45% homology to the human sulfate transporter down-regulated in adenoma encoded by *DRA*, is not a transporter of sulfate, but of chloride and iodine instead.

Given the admission by Applicants that RAFTIN1 is a novel protein with no established function and is without a structural counterpart in Arabidopsis (specification, lines 4-5), its unclear RAFTIN1 proteins from wheat have similar function as that of rice. Further even if RAFTIN1 proteins from wheat function similarly, it is unclear which one of three genes is the true ortholog of osRAFTIN1. It is also unclear whether those three

genes are redundant or not. It is also unclear how to use those transgenic plant other than the rice if reduction of expression of RAFTIN genes would not results in male sterility.

Therefore, in the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to verify the function for RAFTIN1 genes from wheat and to generate a male sterile plant other than rice plant by using recited sequences.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Applicants traverse in the paper filed April 8, 2009. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that Travella et al. demonstrate that RNAi silencing in hexaploid bread wheat has the same effect on all three homoeologous genes(response, page 7, 2nd paragraph).

The Office contends that homoelogous copies of PDS genes are allelic with SNP whereas taRAFTIN1a, taRAFTIN1b, taRAFTIN1d are three different genes with homology in sequence. Therefore the reference Travella et al. are irrelevant.

Applicants argue that Dwivedi et al. demonstrate that homology of the antisense sequence to the gene being silenced need only be on the order of about 70% to result in successful silencing (response, page 7, 1st paragraph).

The Office contends that the requirement for the sequence homology is unpredictable and is gene dependent. Yibrah et al. (1993, Hereditas 118:273-2890) teach that an antisense construct based on the first quarter of the coding sequence from the 5' end , or on the entire coding sequence did not inhibit the synthesis of nopaline whereas effective construct consisted of the 3' terminal sequence from373 to 1565 of the nopaline synthase gene (page 278, last paragraph of the left column).

Summary

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/

Examiner, Art Unit 1638